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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,344	09/02/2005	David J. Kyle	026086.033.210 US	1584
24239	7590	03/11/2008	EXAMINER	
MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709			BERTOGLIO, VALARIE E	
ART UNIT		PAPER NUMBER		
1632				
MAIL DATE		DELIVERY MODE		
03/11/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/532,344	KYLE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 December 2007.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 4-14, 18-33, 37-42, 44 and 45 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3, 15-17, 34-36 and 43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04/22/2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

### **DETAILED ACTION**

Applicant's reply dated 12/05/2007 has been received. Claims 36 and 43 are amended. Claims 4-14,18-33, 47-42,44 and 45 are withdrawn as being drawn to a nonelected invention. Claims 1-3, 15-17, 34-36 and 43 are currently under consideration. Claim 43 is being examined to the extent that it reads on use of a shrimp comprising high-DHA. Other recited limitations are withdrawn as being drawn to non-elected inventions.

This application contains claims 4-14,18-33, 47-42,44 and 45 drawn to an invention nonelected with traverse in the reply filed on 04/19/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### *Specification*

The objections to the disclosure are withdrawn in light of Applicant's amendments to the specification.

#### *Claim Objections*

The objection to claim 36 is withdrawn in light of Applicant's amendments to the claim.

#### *Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,15-17 and 43 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention. The rejection is maintained for reasons of record set forth at pages 4-6 of the office action dated 06/05/2007.

In summary, the state of the art holds that it is unpredictable whether any particular algae will cause an increase in DHA in shrimp fed the algae and the degree of the increase is also variable. The claims require DHA levels of at least 12.5 ug/g fresh weight of shrimp or a DHA/EPA ratio of at least 2.0. Based on the state of the art, only certain feeding conditions would meet these limitations and no feeding conditions have been made of record that lead to a DHA/EPA of at least 2.0. The specification teaches feeding *Cryptocodonium sp.* However, the specification does not teach whether this species of algae results in an increase in DHA to at least 12.5 ug/g fresh weight or the DHA/EPA ratio to at least 2.0. The specification only teaches a modest increase in DHA in 1 out of 2 samples in terms of some percentage relative an unknown standard. It would require undue experimentation to determine how to make the shrimp as claimed comprising at least 12.5 ug/g fresh weight or having a DHA/EPA ratio of at least 2.0 as claimed.

Applicant's arguments have been fully considered and are not found persuasive.

Applicant points to various excerpts of the specification in support of the instant claims and argues that Example 10 is not required to enable the claims as it is provided for the purpose of demonstrating the replacement of convention non-organic sources of DHA with organic sources such as microalgae. Applicant argues that the unpredictability as whether any particular algae will result in increased DHA levels does not support a finding that the claims are not enabled as long as the specification discloses at least one method for =making the invention that bears reasonable correlation to the entire scope of the claims. Applicant argues that Example 1 discloses shrimp production systems including feeds and feeding methods and also describes various sources of DHA. Applicant argues that shrimp fed a defined microalgal source result in shrimp with more than 12.5ug DHA/g fresh weight pt a DHA/EPA ratio of at least 2.0.

In response, the specification provides prophetic teachings of obtaining shrimp with the claimed characteristics of more than 12.5ug DHA/g fresh weight pt a DHA/EPA ratio of at least 2.0. The specification teaches feeding shrimp various specific species of microalgal that “could” (see paragraph 45) increase DHA content shrimp. However, the shrimp made using these methods show only a modest increase in DHA content and the art shows no examples supporting that the claimed levels could ever be obtained. Applicant has directed the Examiner to various excerpts from the specification in support of the claims, however, these excerpts are in reference to general shrimp culture conditions (for example, paragraphs 36 and 42) and fail to support the claim characteristics of more than 12.5ug DHA/g fresh weight pt a DHA/EPA ratio of at least 2.0. Paragraph 48 teaches use of *Cryptocodinium* sp. in feed and that ‘high DHA’ shrimp are harvested. However, this fails to support “more than 12.5ug DHA/g fresh weight pt a DHA/EPA ratio of at least 2.0” as claimed and fails to overcome the state of the art. The only data provided by the specification to demonstrate the result of feeding the various species of high DHA microalgae is that of Table 2 and Applicant has failed to show how this data relates to the claimed more than 12.5ug DHA/g fresh weight pt a DHA/EPA ratio of at least 2.0.

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***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 43 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendment to the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) The rejection of claims 1-3, 34-36 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Thinh *et al* (1999, **Aquaculture**, 170:161-173) is withdrawn in light of Applicant's arguments. The spec defines "shrimp" as claimed as encompassing crustaceans. The shrimp taught by Thinh are brine shrimp (*Artemia*) which are not crustaceans.

2) The rejection of claims 1-3, 34-36 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Barclay *et al* (1996, IDS) is withdrawn in light of Applicant's arguments. The specification defines "shrimp" as claimed as crustaceans. The shrimp taught by Barclay are brine shrimp (*Artemia*) which are not crustaceans.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio, Ph.D./  
Primary Examiner  
Art Unit 1632